

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
2685.1003-008

APPLICATION NO.  
09/822,716

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**

September 12, 2001

(Use several sheets if necessary)

APPLICANT

David A. Edwards and Jeffrey S. Hrkach

FILING DATE

March 30, 2001

GROUP

1615

**COPY**
**U.S. PATENT DOCUMENTS**

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
sk	AA	6,045,828	Apr-4-00	Bystrom et al.	424	489	
	AB	4,895,719	Jan-23-90	Radhakrishnan et al.	424	45	
	AC	5,993,805	Nov-30-99	Sutton et al.	424	94.1	
	AD	5,855,913	Jan-5-99	Hanes et al.	424	489	
	AE	5,985,309	Nov-16-99	Edwards et al.	424	426	
	AF	5,874,064	Feb-23-99	Edwards et al.	424	46	
	AG	6,077,543	20-Jun-00	Gordon et al.	424	489	
	AH	6,001,336	14-Dec-99	Gordon	424	46	
	AI	5,985,248	16-Nov-99	Gordon et al.	424	46	
	AJ	5,976,574	2-Nov-99	Gordon	424	489	
	AK	6,136,295	24-Oct-00	Edwards, et al.	424	45	

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
sk	AL	WO 97/41833	13 Nov 97	PCT			
	AM	WO 96/15814	30 May 96	PCT			
	AN	WO 97/26863	31 Jul 97	PCT			
	AO	WO 97/44012	27 Nov 97	PCT			
	AP	WO 91/16882	14 Nov 91	PCT			
	AQ	WO 98/31346	23 Jul 98	PCT			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

sk	AR	Maa, Y., et al., "Spray-Drying of Air-Liquid Interface Sensitive Recombinant Human Growth Hormone," <i>Journal of Pharmaceutical Sciences</i> Vol. 87(2):152-159 (1998).
	AS	Mumenthaler, M., et al., "Feasibility Study on Spray-Drying Protein Pharmaceuticals: Recombinant Human Growth Hormone and Tissue-Type Plasminogen Activator," <i>Pharmaceutical Research</i> , Vol. 11(1):12-20 (1994).
	AT	Broadhead, J., et al., "The Effect of Process and Formulation Variables on the Properties of Spray-dried $\beta$ -Galactosidase," <i>J. Pharm. Pharmacol.</i> 46:458-467 (1994).

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SEP	AA2	RE37,053 E	13-Feb-01	Hanes, et al.	424	489	
	AB2	6,254,854 B1	3-Jul-01	Edwards, et al.	424	46	
	AC2	5,997,848	12-Jul-99	Patton, et al.	424	46	
	AD2	4,995,385	02-Feb-91	Valentini, et al.	128	203.21	
	AE2	4,069,819	24-Jan-78	Valentini, et al.	128	206	
	AF2	6,098,615	08-Aug-00	Lloyd, et al.	128	200.14	
	AG2	6,080,762	27-Jun-00	Allen, et al.	514	337	
	AH2	5,070,186	3-Dec-91	Joergensen	530	304	
	AI2	5,994,314	30-Nov-99	Eljamal, et al.	514	44	
	AJ2	5,474,978	12-Dec-95	Bakaysa, et al.	514	4	
	AK2	5,504,188	02-Apr-96	Baker, et al.	530	304	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
SEP	AL2	0 655 237 A1	31 May 95	EPO			
	AM2	0 317 120 A1	24 May 89	EPO			
	AN2	2,244,767	18 JAN 97	CAN			
	AO2	WO 00/10541	2-Mar-00	PCT			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

SEP	AU	Patton, J. and Platz, R., "(D) Routes of Delivery: Case Studies (2) Pulmonary Delivery of Peptides and Proteins for Systemic Action," <i>Advanced Drug Delivery Reviews</i> , 8:179-196 (1992).
	AV	Niven, R., "Delivery of Biotherapeutics by Inhalation] Aerosol," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 12(2&3):151-231 (1995).
	AW	Lo et al., "Protein Location in Liposomes, A Drug Carrier: A Prediction by Differential Scanning Calorimetry," <i>Journal of Pharmaceutical Sciences</i> , 84(7):805-814 (1995)

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AP	AA3	5,534,488	09-Jul-96	Hoffmann	514	3	
	AB3	5,972,331	26-Oct-99	Reichert et al.	424	85.1	
	AC3	5,547,929	20-Aug-96	Anderson, Jr., et al.	514	3	
	AD3	5,461,031	24-Oct-95	DeFelippis	514	4	
	AE3	4,459,226	10-Jul-84	Grimes, et al.	260	112.7	
	AF3	5,941,240	24-Aug-99	Gonda, et al.	128	200.14	
	AG3	5,970,973	26-Oct-99	Gonda, et al.	128	200.14	

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AP	AX	Vanbever et al., "Formulation and Physical Characterization of Large Porous Particles for Inhalation," <i>Pharmaceutical Research</i> , 16(11):1735-1742 (1999)					
	AY	Edwards, "The Macrotransport of Aerosol Particles in The Lung: Aerosol Deposition Phenomena," <i>J. Aerosol Sci.</i> , 26(2):293-317 (1995)					
	AZ	Edwards et al., "Large Porous Particles for Pulmonary Drug Delivery," <i>Science</i> , 276:1868-1871 (1997)					
	AR2	French et al., "The Influence of Formulation on Emission, Deaggregation and Deposition of Dry Powders for Inhalation," <i>J. Aerosol Sci.</i> , 27(5):769-783 (1996)					
	AS2	Hanes et al., "Porous Dry-Powder PLGA Microspheres Coated With Lung Surfactant For Systemic Insulin Delivery VIA The Lung," <i>Proceed Int'l. Symp. Control Rel. Bioact. Mater.</i> , pp.57-58 (1997)					
	AT2	Gupta et al., "Physical Characterization of Large Porous Particles for Inhalation," <i>Pharmaceutical Research</i> , (2000)					

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JP	AU2	Vanbever et al., "Letter to the Editor", <i>Pharmaceutical Research</i> , (2000)
	AV2	Mintzes, "The Spray Drying of Large, Porous Particles for Aerosol Drug Delivery to The Lung," <i>The Pennsylvania State University, University Scholars Program</i> , pp. 1-44, Thesis for baccalaureate degree (1998)
	AW2	Wang et al., "Inhalation of Estradiol for Sustained Systemic Delivery," <i>J. of Aerosol Medicine</i> , 12(1):27-36 (1999)
	AX2	Damgé, C., et al., "New Approach for Oral Administration of Insulin With Polyalkylcyanoacrylate Nanocapsules as Drug Carrier", <i>Diabetes</i> , 37:246-251 (1988)
	AY2	Ben-Jebria et al., "Large Porous Particles for Sustained Protection from Carbachol-Induced Bronchoconstriction in Guinea Pigs", <i>Pharmaceutical Research</i> , 16(4):555-561 (1999)
	AZ2	Andya et al., "The Effect of Formulation Excipients on Protein Stability and Aerosol Performance of Spray-Dried Powders of a Recombinant Humanized Anti-IgE Monoclonal Antibody," <i>Pharmaceutical Research</i> , 16(3):350-358 (1999)
	AR3	Broadhead, J., et al., "The Spray Drying of Pharmaceuticals," <i>Drug Development and Industrial Pharmacy</i> , 18(11&12):1169-1206 (1992)
	AS3	Nice, "Aerosol Properties of Large, Porous Particles for Inhalation," <i>The Pennsylvania State University, University Scholars Program</i> , pp. 1-59, Thesis for baccalaureate degree, (1998)
	AT3	Niven et al., "Abstracts for the International Society for Aerosols in Medicine 12 <sup>th</sup> Biennial Congress," <i>J. of Aerosol Med.</i> , 12(2) sec. 73 (1999)
	AU3	Johnston et al., "Abstracts for the International Society for Aerosols in Medicine 12 <sup>th</sup> Biennial Congress," <i>J. of Aerosol Med.</i> , 12(2) sec. 84 (1999)
	AV3	Scheuch et al., "Abstracts for the International Society for Aerosols in Medicine 12 <sup>th</sup> Biennial Congress," <i>J. of Aerosol Med.</i> , 12(2) sec. 138 (1999)

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AW3	Li et al., "Aerodynamics and Aerosol Particle Deaggregation Phenomena In Model Oral-Pharyngeal Cavities," <i>J. Aerosol Sci.</i> 27(8):1269-1286 (1996).
AX3	Kawaguchi, H., et al., "Phagocytosis of Latex Particles by Leukocytes. I. Dependence of Phagocytosis on the Size and Surface Potential of Particles," <i>Biomaterials</i> 7:61-66 (1986)
AY3	Krenis, L.J. and B. Strauss, "Effect of Size and Concentration of Latex Particles on Respiration of Human Blood Leucocytes," <i>Proc. Soc. Exp. Med.</i> , 107:748-750 (1961)
AZ3	Heyder, J., et al., "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 $\mu$ m," <i>J. Aerosol. Sci.</i> , 17(3):811-825 (1996)
AR4	Visser, J., "An Invited Review: Van der Waals and Other Cohesive Forces Affecting Power Fluidization", <i>Powder Technology</i> , 58:1-10 (1989)
AS4	Gonda, I., "Aerosols for Delivery of Therapeutic and Diagnostic Agents to the Respiratory Tract," in <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 6:273-313 (1990)
AT4	Gonda, I., "Physico-chemical Principles in Aerosol Delivery," in <u>Topics in Pharmaceutical Sciences</u> 1991, Crommelin, D.J. and K.K. Midha, Eds., Medpharm Scientific Publishers, Stuttgart, pp. 95-117 (1992)
AU4	Morén, F., "Aerosol Dosage Forms and Formulations," in <i>Aerosols in Medicine. Principles, Diagnosis and Therapy</i> , Morén, et al., Eds, Elsevier, Amsterdam, 1985
AV4	Heinemann, L., et al., "Time-action Profile of Inhaled Insulin," <i>Diabetic Medicine</i> , 14:63-72 (1997)
AW4	Abstract from: Derwent Info ltd., Access No. 1995-195390 / 199526

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David A. Edwards and Jeffrey S. Hrkach

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March 30, 2001

CONFIRMATION NO.  
7248

GROUP  
1615

January 27, 2003

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U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
AH3		5,898,028	27 AP 1999	Jensen et al.
AI3				
AJ3				
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AA4				
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	AL						
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